

REGULATIONS RESTRICTING THE AGE OF SALE FOR NICOTINE INHALING PRODUCTS TO OVER EIGHTEENS

CONSULTATION DOCUMENT

September 2017

Purpose of the consultation

- 1. The purpose of this consultation is to seek views from the public and interested parties on the detail of draft regulations which propose to restrict the age of sale for nicotine inhaling products to persons over the age of eighteen. This legislation will bring these products into line with other age-restricted products such as tobacco and alcohol.
- 2. The use of e-cigarettes has grown significantly in popularity in the past 5 years. While the Department accepts that they may have a role to play in harm reduction, it is concerned by evidence which shows they are being used by children and young people. In February 2016, the Northern Ireland Assembly voted in favour of legislation giving the Department of Health powers to make regulations which would restrict the age of sale of nicotine containing products, such as e-cigarettes, to over-eighteens. These regulation-making powers can be found at section 1 of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016 (the Act).
- 3. The Department has now drafted regulations in order to implement restrictions on the sale of e-cigarettes. In summary, the regulations create 2 new offences: that of selling nicotine inhaling products to a person under the age of 18 and the offence of purchasing a nicotine inhaling product on behalf of a minor, otherwise known as proxy purchasing. The legislation will exempt the sale of a nicotine inhaling product which is licensed as a medicine, where it has been prescribed to a child or where the medicine is indicated for use by children. The regulations will be enforced by local district councils.
- 4. A previous consultation carried out on the draft Health (Miscellaneous Provisions) Bill in 2014, sought views on whether there should be age restrictions applied in relation to the sale of nicotine inhaling products. The outcome of that consultation was overwhelmingly in favour of such restrictions. This consultation, therefore, does not seek views on whether age restrictions should be applied, but is seeking views on the details of the proposed regulations, including the exemptions.
- 5. The consultation will run from 4 September to 27 October 2017. All responses must be received into the Department by 5pm on the closing date. Information on how to respond is set out on page 9.

Background

6. Since 2011, the popularity of nicotine inhaling products, the most popular of which are e-cigarettes, has grown exponentially. A recent survey carried out in Northern Ireland¹, showed that 16% of adults here have tried e-cigarettes at least once and that 6% of the population currently use them (over 85,000 people). Reasons given for using them vary from health reasons i.e. to quit smoking or to reduce the number of cigarettes smoked, to financial reasons (they are cheaper than cigarettes).

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¹ Northern Ireland Health Survey 2015/16 - NISRA

- 7. Given that e-cigarettes are relatively new products, there are no legal restrictions in Northern Ireland regarding who can purchase them or where they can be used. However, the revised EU Tobacco Products Directive¹, which was implemented across the UK from May 2016, does introduce a number of requirements for e-cigarettes in order to ensure that they are safer for use by consumers. Key measures in the EU Directive relate to unlicensed nicotine inhaling products and include:
 - a limitation on the nicotine content of e-liquids;
 - a requirement for manufacturers and importers to report on ingredients in, and emissions resulting from, the use of e-cigarettes and provide toxicological data:
 - a requirement for the provision of information to consumers, including a health warning on packaging; and
 - restrictions on cross-border advertising and promotion including a ban on advertising on television, radio and the internet.

What are e-cigarettes?

- 8. E-cigarettes are battery operated devices which deliver nicotine, as well as flavourings and other chemicals, to the user. The process does not involve combustion, therefore there is no smoke. However, an aerosol or "vapour" is produced, which is then inhaled, leading to the term "vaping" being commonly used to describe the practice of using an e-cigarette. Typically, as well as nicotine and flavourings, the e-cigarette liquid contains water and propylene glycol or glycerine.
- 9. E-cigarettes first appeared on the market in China in 2004 and, shortly after, were introduced into Europe. Their increase in popularity coincided with legislative bans on smoking in enclosed public and work places. The early versions resembled tobacco cigarettes but the products have evolved considerably since then and the most popular versions today bear little resemblance to the early prototypes.
- 10. At present, there are 3 types of e-cigarette products on the market. These are:
 - i. Disposable e-cigarettes which generally resemble tobacco cigarettes or pens. They are for single use only and are non-rechargeable.
 - ii. Rechargeable e-cigarettes which use replaceable liquid-filled cartridges
 like disposable e-cigarettes, these products also tend to resemble cigarettes or pens.
 - iii. Rechargeable e-cigarettes complete with refillable tank or reservoir. These are known as third generation devices and are the most popular with vapers.

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¹http://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf

11. In 2014, it was estimated that there were around 466 brands of e-cigarettes and 7764 unique flavours available worldwide¹. The requirement under the EU Tobacco Products Directive for manufacturers and importers of e-cigarette products to submit product information to nominated authorities may, in time, reduce the number of brands and individual flavours on the market.

E-cigarette use amongst adults

- 12. Survey data in relation to adult e-cigarette use has been collected in Northern Ireland since 2013/14. In the first year, questions were only asked of current and ex-smokers and 33% reported having ever used an e-cigarette. The main reasons given for using them were to quit smoking (12%), to reduce the number of cigarettes smoked (44%) and to allow them to smoke indoors (15%).
- 13. From 2014/15, all respondents of the Health Survey NI were asked whether they had ever used an e-cigarette and whether they used one currently. The percentage of ever users grew from 14% in 2014/15 to 16% in 2015/16 with current users growing slightly from 5% to 6%. The vast majority (approximately 97%) of users were current or ex-smokers, therefore, e-cigarette use by never smokers remains low.
- 14. The main reason reported for using e-cigarettes in both 14/15 and 15/16 was to reduce the number of cigarettes smoked. Users also stated that the cheaper price of e-cigarettes and using them to quit tobacco completely were incentives. In terms of intentions to quit using e-cigarettes, in 14/15 the majority of respondents had no plans to quit within the coming 6 months (65%). This had increased to 79% by 15/16.
- 15. Figures available from ASH UK² reveal that e-cigarette use amongst adults in Northern Ireland is on a comparable level with use in Great Britain, with 6% of the adult population using them. Of these, 52% are ex-smokers while 45% continue to use tobacco alongside e-cigarette use. The main reasons given for using e-cigarettes were the same as those provided by respondents to the Northern Ireland survey.

E-cigarette use amongst children

16. Questions on e-cigarette use were included in the Young Persons Behaviour and Attitudes Survey for the first time in 2016. The results from this survey³ reveal that awareness of e-cigarette use amongst adolescents in Northern Ireland is very high, with 94% of 11-16 years reported to have heard of them. In terms of use, 20% of children surveyed had used an e-cigarette at some point, with 5% claiming to have used one within the past week.

¹ Zhu S, Sun JY, Bonnevie E, *et al* – Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation – Tobacco Control 2014;23:iii3-iii9.

² ASH Fact Sheet on the use of electronic cigarettes among adults in Great Britain – May 2017.

³ NISRA – June 2017 - Young Persons Behaviour and Attitudes Survey 2016 – Topline Results

- 17. When compared with tobacco use, the survey shows that more young people have tried e-cigarettes, with ever use for cigarettes being reported at 14%. However, regular use of cigarettes is slightly higher with 2.3% of 11-16 year olds stating that they smoke cigarettes every day compared with 1.4% who use an e-cigarette each day.
- 18. Other surveys have also been carried out across the rest of the UK. Information collected among 11-18 year olds through the Smokefree GB Youth Survey¹ revealed that, in 2016, 12% had tried e-cigarettes at least once. More young people had experimented with cigarettes (19%) and of those who tried e-cigarettes, 57% had already tried tobacco first. Regular use (once a month or more) was rare and largely among children who were either current smokers or had smoked in the past. Amongst this age group, the most popular product was the rechargeable e-cigarette with the refillable tank, followed by the rechargeable with pre-filled cartridge.

E-liquids

- 19. E-liquids are available for sale in a number of outlets, including newsagents, convenience stores, supermarkets, pharmacies, specialised vaping shops, market stalls and car boot sales. The 2014 EU Tobacco Products Directive (TPD) prohibits the sale of e-liquids in quantities larger than 10ml and limits the nicotine content to 20mg/ml for unlicensed products. From 20 May 2017, no e-liquids should be for sale in Northern Ireland which do not comply with these requirements.
- 20. There are over 7,000 unique flavours of e-liquid available worldwide. They include: tobacco; menthol; fruit; chocolate; vanilla; cola; peanut butter; and bubble gum. Most varieties are available in a range of nicotine strengths. A number of flavours are also available nicotine-free. According to the ASH Smokefree GB survey, among adult vapers, only 6% of e-cigarette users report using liquids containing more than 20mg/ml of nicotine, i.e. over the threshold permitted for unlicensed products under the TPD.
- 21. Fruit flavoured e-liquids were the most popular among young people surveyed², particularly those who no longer used e-cigarettes and those who have never smoked (49%). Among current users, fruit is also the most popular (36%) followed by energy drink/soft drink flavour (11%) and menthol tobacco flavour (7%).
- 22. The latest survey results for adults showed a rise in the number of users favouring fruit flavours (29%) as they beat tobacco flavour (25%) to become the most popular in 2017. Menthol flavour was also popular amongst adults with a quarter of all users choosing it.

¹ ASH fact sheet on the use of electronic cigarettes among children in Great Britain – October 2016

² Smokefree GB Youth Survey – March and April 2016

Licenced nicotine products

- 23. A range of licenced nicotine products, more commonly known as nicotine replacement therapy or NRT, has been available in Northern Ireland since the early 1980s. These products, which have been granted medicines licensing by the Medicines and Healthcare products Regulatory Agency (MHRA), can be marketed as smoking cessation aids and are available on prescription.
- 24. At present, the only licenced nicotine *inhaling* product currently on the market in the UK is the Nicorette Inhalator. It is expected to be joined shortly by a second inhaler product Voke which is the first e-cigarette to be granted a medicines licence.
- 25. Licenced nicotine products are subject to different regulatory rules than unlicensed e-cigarettes and may either be licensed for sale to persons under the age of 18 or can be made available to minors on prescription. The proposed new age of sale restrictions will only apply to unlicensed products.

Need for legislation

- 26. In Northern Ireland, at present, there are no restrictions on the sale of ecigarettes. This is not the case in the rest of the UK where they are now prohibited for sale to under eighteens. A number of e-cigarette products are marked by their manufacturers as only suitable for use by adults and most responsible retailers will refuse to sell them to under eighteens, however, a consistent approach in the form of a minimum age of sale requirement is preferable.
- 27. E-cigarette use has been estimated as being 95% safer than tobacco use in a 2015 Public Health England report¹. However, the relative newness of these products means that the long-term effects of inhaling the chemicals present in e-cigarettes is still unknown. For smokers who find they cannot give up tobacco, e-cigarettes would certainly appear to present a less harmful option but their use by non-smokers is strongly discouraged.
- 28. While e-cigarettes do not contain many of the harmful components of tobacco, they do contain nicotine. Nicotine is highly addictive and according to the World Health Organisation, exposure to nicotine whilst still in adolescence can lead to long-term consequences for brain development². As a result, the WHO recommends that the sale and/or distribution of e-cigarettes to minors is banned.
- 29. In addition to the potential long-term health implications of e-cigarette use by teenagers, there are also concerns that they may act a gateway into smoking. Youth smoking prevalence in Northern Ireland has been steadily decreasing in recent years, from 14% in 2000 to 5% in 2013. The Department does not wish to see this trend reversed by young people, who may not have been induced initially to smoke tobacco, becoming addicted to nicotine through e-cigarettes. While the

¹ E-cigarettes – an evidence update – Public Health England – August 2015

² Document FCTC/COP/7/11 (available at www.who.int/fctc/publications).

current evidence does not support the gateway theory, e-cigarettes are a relatively new product, and the age of sale regulations are aimed at preventing this from happening.

Detail of proposed regulations

- 30. Regulations will be made in accordance with Section 1 of the Heath (Miscellaneous Provisions) Act (Northern Ireland) 2016. The draft regulations are set out in **Annex A** and should be read in conjunction with the Act.
- 31. The minimum age of sale of 18 years will apply to "nicotine inhaling products" (NIPs). This definition, which is the same as that used in similar regulations introduced in England and Wales from 1 October 2015, covers all e-cigarette devices and their refills. Within the regulations, a "nicotine inhaling device" covers any device which is intended for the purpose of enabling nicotine to be inhaled through a mouth piece, regardless of how they are powered. The device will still be covered by the regulations even if the user intends it for the purposes of inhaling non-nicotine containing e-liquids.
- 32. The proposed regulations do not cover component parts such as batteries, charging devices and electrical leads for NIPs.

Medical products or medical devices

- 33. The regulations provide exemptions for any nicotine inhaling product which is licensed as a medicine by MHRA. Products which are licensed as medicines can be made available to children and young people under the age of 18 years old on prescription. The draft regulations also propose an exemption for any nicotine inhaling product which has a marketing authorisation indicating that it is suitable for use by persons under the age of 18.
- 34. Regulation 5 is intended to exempt the sale of NIPs which are medicines or medical devices sold in accordance with a valid prescription by a pharmacist (or in other rare exceptional circumstances under which prescription only medicines could be sold). Regulation 6 will exempt licensed nicotine inhaling products which are indicated for use by under eighteens and are available for general sale. In such cases, the seller may not need to be a pharmacist, as general sales list medicines can be sold in any type of shop, subject to certain conditions being met.
- 35. The draft regulations do not cover other nicotine replacement therapy medicines which are not intended to be inhaled through a mouth piece, e.g. nicotine gum or patches.

Proxy purchase of e-cigarettes

36. Section 1 of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016 also contains regulation-making powers in relation to the proxy purchasing of nicotine inhaling products. The draft regulations will make it an offence for an adult to purchase a nicotine inhaling product on behalf of a child, unless it has

- been prescribed for that child. This will bring the purchase of NIPs into line with other age-restricted products such as tobacco and alcohol.
- 37. The proxy purchase offence could also apply to some NIPs which are licensed as medicines. For example, where a product is licensed for general sale but is indicated for use by over eighteens only, it would be an offence for an adult to purchase such a product on behalf of a child.
- 38. As is the case with tobacco and alcohol, the adult making the purchase on behalf of the child would be committing the offence and not the retailer who has sold the product.

Offences and penalties

- 39. Section 1 of the Act sets out the penalty which would apply where an offence is committed in relation to the sale of a nicotine inhaling product to a minor. The draft regulations amend Article 4A of the Health and Personal Social Services (Northern Ireland) Order 1978 in order to apply the offence of an adult purchasing a nicotine inhaling product on behalf of a child. The penalty associated with this offence is set out in Article 4A(2) of the 1978 Order.
- 40. Enforcement authorities will have the option of issuing fixed penalty notices for either offence in relation to the sale of nicotine inhaling products. It is proposed that the amount of the penalty for both offences i.e. selling a NIP to a person under 18, and the offence of proxy purchasing would be £250. This mirrors similar existing penalties for tobacco sales offences.
- 41. Failure to pay a fixed penalty notice could result in the matter being referred to a court. On conviction of either offence, a court can award a fine up to a maximum of level 5 on the standard scale (currently £5,000).
- 42. Schedule 1 of the Act integrates the sale of nicotine inhaling products into the existing enforcement regime relating to the persistent commission of tobacco offences. A person or a business found to be repeatedly selling NIPs to children could receive a Restricted Sales Order or a Restricted Premises Order from the court. Such an order can prohibit the sale of a nicotine inhaling product by a named individual or a business premises for up to 3 years.
- 43. Section 1 of the Act provides for a defence whereby the retailer is able to demonstrate that all reasonable steps were taken to avoid committing the offence.

Enforcement

44. The enforcement of the draft regulations will be the responsibility of authorised officers of district councils.

Equality impact assessment and human rights

45. The aim of the measures in the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations is to prevent children and young people from becoming addicted to nicotine and from nicotine inhaling products acting as a gateway into smoking for young people. The Department carried out a preliminary screening of the policy proposals and, as part of the screening process, concluded that an Equality Impact Assessment was not necessary. The Department is content that that there will be no adverse impact on any of the groups listed under section 75 of the Northern Ireland Act 1998 as a result of the policy.

Regulatory impact assessment

46. A consultation stage regulatory impact assessment has been prepared and is attached at **Annex B**. Any comments on the draft RIA would be very welcome as would any further evidence or information on the impact the proposed regulations would have on businesses.

Consultation – how to respond

- 47. If you wish to respond to this consultation, please do so by completing and returning the response questionnaire at **Annex C**. The questionnaire may also be downloaded from the e-consultation section of the Department's website: (https://www.health-ni.gov.uk/consultations).
- 48. Additional copies of the consultation document can be obtained by contacting the Department's Population Health Administration Team (contact details below).
- 49. If you require any of these documents in another format or language, please contact the Department's Population Health Administration Team.
- 50. The closing date for responses is **5pm on Friday 27 October 2017**. Responses received after this date will only be considered in exceptional circumstances and with prior agreement from the Department.
- 51. The completed response questionnaire can be returned via e-mail or post and all queries you may have regarding this consultation should be addressed to the Department's Population Health Administration Team.

Phone: 028 9052 8385 or 028 9052 2059 E-mail: phdconsultation@health-ni.gov.uk

Address: Population Health Directorate Administration Team

Department of Health

Room C4.22 Castle Buildings

Belfast BT4 3SQ 50. Please ensure that the completed response questionnaire includes: your name, organisation (if relevant), address, telephone number and email (if applicable), and whether your comments represent your own views or the corporate views of your organisation.

Draft Regulations laid before the Assembly under Section 18(1) of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016 for approval

DRAFT STATUTORY RULES OF NORTHERN IRELAND

2017 No.

PUBLIC HEALTH

The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations (Northern Ireland) 2017

Made - - - - Xth XXXXX 2017

Coming into operation Xth XXXXX 2017

The Department of Health makes the following Regulations, in exercise of the powers conferred by sections 1(1) and (6), and 3(2) of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016(a).

Citation, commencement and interpretation

- 1.—(1) These Regulations may be cited as the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations (Northern Ireland) 2017 and shall come into operation on X XXXXX 2017.
- (2) In these Regulations-
- "marketing authorisation" has the meaning given by regulation 8(1) of the Human Medicines Regulations $2012(\mathbf{b})$;
- "medical device" has the meaning given by regulation 2(1) of the Medical Devices Regulations $2002(\mathbf{c})$;
- "medicinal product" has the meaning given by regulation 2(1) of the Human Medicines Regulations 2012;
- "nicotine cartridge" means a cartridge which-
- (a) contains a substance which is not tobacco (d) but consists of, or contains, nicotine, and
- (b) is intended to form part of a nicotine inhaling device;
- "nicotine inhaling device" means a device which-
- (a) is intended to enable nicotine to be inhaled through a mouth piece (regardless of whether the device is also intended to enable any other substance to be inhaled through a mouth piece),but
- (b) is not tobacco, cigarette papers or a device intended to be used for the consumption of lit tobacco;

(b) S.I. 2012/1916. Relevant amendments were made by S.I. 2013/235, 1855 & 2593, S.I. 2014/490 & 1878, S.I. 2015/354, 895 & 1503, and S.I. 2016/186, 190 & 696.

⁽a) 2016 c.26.

⁽c) S.I. 2002/618. Relevant amendment was made by S.I. 2008/2936.

⁽d) See the definition of "tobacco" in Article 7 of the Health and Personal Social Services (Northern Ireland) Order 1978 (S.I. 1978/1907 (N.I. 26))

"nicotine inhaling product" means a nicotine inhaling device, nicotine cartridge or nicotine refill substance;

"nicotine refill substance" means a substance which-

- (a) is not tobacco but consists of, or contains, nicotine and
- (b) is intended to be used to refill a nicotine inhaling device;

"parallel import licence" has the meaning given by regulation 48(2) of the Human Medicines Regulations 2012;

"prescription only medicine" has the meaning given by regulation 8(1) of the Human Medicines Regulations 2012.

Proxy purchase of nicotine products

- **2.**-(1) Article 4A of the Health and Personal Social Services (Northern Ireland) Order 1978(a) (purchase of tobacco on behalf of persons under 18) is amended in accordance with paragraphs (2) and (3).
 - (2) In the heading, after "tobacco" insert "or nicotine products".
 - (3) In paragraph (1), for "or cigarette papers" substitute ", cigarette papers or a relevant nicotine product".

Interpretation of "relevant nicotine product"

3. Article 7 of the Health and Personal Social Services (Northern Ireland) Order 1978 (interpretation) is amended by inserting at the appropriate place-

""relevant nicotine product" means a nicotine product within the meaning of section 7 of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016 the sale of which to persons aged under 18 is for the time being prohibited by regulations under section 1(1) of that Act;".

Prohibition of sale of nicotine inhaling products to persons aged under 18

4. The sale of nicotine inhaling products to persons aged under 18 is prohibited, except where regulation 5 or 6 applies.

Exception for sales of medicines and medical devices in accordance with a prescription etc.

- 5.- (1) This regulation applies to the sale of a nicotine inhaling product where –
- (a) the nicotine inhaling product is a medicinal product or a medical device; and
- (b) the circumstances of the sale are such that it would be permitted under Part 12 of the Human Medicines Regulations 2012 (dealings with medicinal products) if the nicotine inhaling product were a prescription only medicine.
- (2) For the purposes of paragraph (1)(b), Part 12 of the Human Medicines Regulations 2012 is to be read as if regulation 244 (exemption in cases involving another's default) were omitted.

Exception for medicines indicated for the treatment of persons aged under 18

- **6.** -(1) This regulation applies to the sale of a nicotine inhaling product which-
- (a) is an authorised medicinal product; and
- (b) is indicated for the treatment of persons of the age of the person to whom the product is sold.
- (2) For the purposes of this regulation-
- (a) a product is indicated for the treatment of persons of a particular age if it is described as such in the summary of the product characteristics for the product in accordance with

⁽a) S.I. 1978/1907 (N.I. 26), Article 4A was inserted by the Tobacco Retailers Act (Northern Ireland) 2014 (2014 c.4)

paragraph 27 of Schedule 8 to the Human Medicines Regulations 2012 (summary of the product characteristics) or Article 11 of Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community code relating to medicinal products for human use (a);

- (b) "the summary of the product characteristics" is to be construed in accordance with Article 11 of Directive 2001/83/EC;
- (c) a medicinal product is "authorised" if one of the following is in force for the product-
- (i) a marketing authorisation; or
- (ii) a parallel import licence.

Review

- 7. (1) Before the end of the review period, the Department of Health must –
- (a) carry out a review of these Regulations,
- (b) set out the conclusions of the review in a report, and
- (c) publish the report.
- (2) The report must in particular –
- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations,
- (b) assess the extent to which those objectives are achieved, and
- (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.
- (3) "Review period" means the period of three years beginning with the day on which section 6 of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016 is commenced.

Sealed with the Official Seal of the Department of Health on xx xxxxx 2017.



Name
A senior officer of the
Department of Health

⁽a) Directive 2001/83/EC (OJ No. L311, 28.11.2001) as amended by Directive 2012/26/EU (OJ No. L299, 27.10.2012, p.1.)

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, made under section 1 of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016, contain provisions to make it an offence to sell nicotine inhaling products to persons aged under 18 and for an adult to purchase nicotine inhaling products on behalf of a person aged under 18.

Regulation 2 amends Article 4A of the Health and Personal Social Services (Northern Ireland) Order 1978. Under that Article, it is an offence for an adult to purchase tobacco or cigarette papers on behalf of someone under 18. That Article is amended so that it is also an offence for an adult to purchase relevant nicotine products on behalf of someone under 18.

Regulation 3 amends Article 7 of the Health and Personal Social Services (Northern Ireland) Order 1978 to include a definition of a relevant nicotine product.

Regulation 4 prohibits the sale of nicotine inhaling products to someone under the age of 18.

Regulation 5 provides for an exception to the prohibition in regulation 4 if the product is licenced as either a medicinal product or a medical device and is sold by prescription.

Regulation 6 provides for an exception to the prohibition in regulation 4 if the product is an authorised medicinal product which has been indicated for the treatment of persons that are of the age of the person the product is sold to.

Regulation 7 provides for a review to be carried out of the prohibition on the sale of nicotine products to persons under 18.

DRAFT STATUTORY RULES OF NORTHERN IRELAND

2017 No.

PUBLIC HEALTH

The Tobacco Retailer (Fixed Penalty) (Amount) (Amendment) Regulations (Northern Ireland) 2017

Made - - - - XXth XXXXX 2017

Coming into operation - XXth XXXXX 2017

The Department of Health makes the following Regulations, in exercise of the powers conferred by sections 12(8) and 24(3) of the Tobacco Retailers Act (Northern Ireland) 2014 (a).

Citation, commencement and interpretation

3. These Regulations may be cited as the Tobacco Retailer (Fixed Penalty) (Amount) (Amendment) Regulations (Northern Ireland) 2017 and shall come into operation on *Xth XXXXXX* 2017.

Amendment of the Tobacco Retailer (Fixed Penalty) (Amount) Regulations (Northern Ireland) 2016

4. For the Schedule to the Tobacco Retailer (Fixed Penalty) (Amount) Regulations (Northern Ireland) 2016(**b**) (amount of fixed penalty), substitute the Schedule to these Regulations.

Sealed with the Official Seal of the Department of Health on XXth XXXXX 2017



Name Senior officer of the Department of Health

(**b**) SR 2016 No. 180

⁽a) 2014 c.4 (N.I.)

Amount of Fixed Penalty

	(1)	(2)
	Offence	Fixed
	Offence	Penalty
1	An unregistered person carrying on a tobacco business (section 10 (1) of the Act).	£500.00
2	A registered person carrying on a tobacco business at premises other than those noted in the person's entry in the Register (section 10(2) of the Act).	£500.00
3	A person who fails, without reasonable excuse, to comply with section 3 (duty to notify certain changes) (section 10(3) of the Act)	£50.00
4	A person who fails, without reasonable excuse, to comply with section 8(2) (in relation to the display of a notice if subject to a restricted premises order) (section 10(7) of the Act).	£100.00
5	A person who fails, without reasonable excuse, to comply with section 9(2) (in relation to removal of tobacco or cigarette papers from the retail area where a restricted premises order has effect) (section 10(8) of the Act).	£500.00
6	A person who sells to a person under the age of 18 any tobacco or cigarette papers, whether for his own use or not (article 3 of the 1978 Order)(a).	£250.00
7	A person who sells to a person under the age of 18 any nicotine inhaling products, whether for his own use or not (section 1 of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016)(b).	£250.00
8	Failure to comply with a court order made in relation to the control of an automatic machine for the sale of tobacco (article 4 of the 1978 Order).	£250.00
9	A person aged 18 or over who knowingly buys or attempts to buy tobacco, cigarette papers or a relevant nicotine product on behalf of a person under the age of 18 (article 4A of the 1978 Order)(c).	£250.00
10	A person carrying on a retail business who sells cigarettes to any person other than pre-packed cigarettes in their original package (article 4 of the 1991 Order).	£250.00
11	Failure to comply with the prohibition of the sale of tobacco from an automatic machine (article 4A of the 1991 Order)(d).	£250.00
12	Failure to display a notice stating "It is illegal to sell tobacco products to anyone under the age of 18" in retail premises where tobacco is sold (article 5 of the 1991 Order)(e).	£100.00

Article 3 was amended by the Children and Young Persons (Sale of Tobacco etc.) Regulations (Northern Ireland) 2008 (S.R. 2008 No. 306) and section 18(2) of the Tobacco Retailers Act (Northern Ireland) 2014. (**a**)

⁽b) 2016 c. 26 (N.I.)

Article 4A was inserted by section 18(3) of the Tobacco Retailers Act (Northern Ireland) 2014 (c)

 $^{(\}mathbf{d})$

Article 4A was inserted by section 23 of the Health Act 2009 (2009 c. 21).

Article 5 was amended by the Children and Young Persons (Sale of Tobacco etc.) Regulations (Northern Ireland) 2008 (S.R. 2008 No. 306).. (**e**)

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Tobacco Retailer (Fixed Penalty) (Amount) Regulations (Northern Ireland) 2016.

Regulation 2 replaces the Schedule to the Tobacco Retailer (Fixed Penalty) (Amount) Regulations (Northern Ireland) 2016 to allow for the inclusion of amounts of fixed penalties for offences relating to the sale or proxy purchase of nicotine containing products.